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Title : Insights on Patient-Centric specification setting and implementation for Vaccines

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BACKGROUND

Specification setting is a critical deliverable in the development of any new pharmaceutical product. As discussions are on-going to revise the main guidance documents on this topic (ICH Q6A & 6B), the concept of Patient-Centric Specification (PCS) has been at the center of key discussions in pharmaceutical industry during the recent years (notably, at the *IABS Conference on Global Harmonized Specifications: current state and future opportunities*, 2023).

CHALLENGES

In a recent position paper published by EFPIA (June 2023), PCS was defined as "*a set of CQAs and acceptance ranges to which product quality attributes should conform for the product to be safe and effective when used as labeled*". Yet, it is not always straightforward to link the quality attributes to the clinical outcomes; moreover, it seems impossible to define a unique standard approach for PCS determination, considering the diversity of pharmaceutical products and their mechanisms of action, along with the different types of associated quality attributes. Finally, the more traditional procedure consisting in deriving acceptance ranges from variability observed in manufacturing history may still be considered as the preferred approach for file submission.

PROPOSED APPROACH

This talk will notably give an overview of advantages of PCS approach compared to the more traditional one, with emphasis on implementation of QbD principles for pharmaceutical development. The talk will be focused on application for Vaccines products, and will provide some illustrative examples for different product families and attributes.